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(54) **Device in powder inhalators.**

(57) Device in a previously known powder inhalator intended for inhalation of an air flow which contains pharmacologically active compound in micronized form. The powder inhalator comprises a nozzle unit (2) with a nozzle aperture (2a) as well as a container unit (3) with a releasing or dosing unit (6) for delivering the active compound. The air flow generated by inhalation is at least partly aspirated through an air conduit (7) located in the container unit (3), which conduit extends from an air inlet (8), communicating with the environment, via said releasing or dosing unit (6), up to said nozzle unit (2). According to the invention, deflector devices are stationarily arranged in the container unit (3) and/or in the nozzle unit (2), said deflector devices, for example in the shape of a helical channel portion (13), being arranged to create a powerful deflecting movement for the purpose of disrupting said powder particles into the respirable particle size distribution (less than 5 μm).

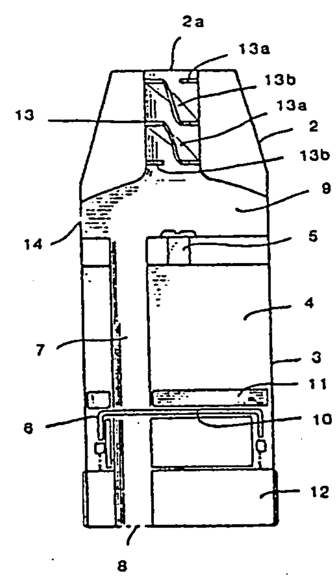

Fig. 1

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Description

Device in powder inhalators

The present invention relates to a device in powder inhalators intended to be used for local administration of drugs to the respiratory tract and lungs of a patient.

There are different types of powder inhalators, for example those which operate with hard gelatine capsules from which the pharmacologically active compound is released during inhalation through the inhalator, and those which dose the pharmacologically active compound directly into the air conduit by means of a special dosing unit, said compound being administered to patients during inhalation through the inhalator.

All substances which are used in such inhalators are atomized or micronized so that the main fraction of the substance is within the particle size range which is termed the respirable range, that is, particles smaller than 5 µm. This applies both to inhalators operating with pure active compound and to those where the active compound is mixed with suitable diluting agents such as lactose, sucrose etc.

The active compound is enclosed, without carrier substance or when appropiate together with carrier substance, in hard gelatine capsules or directly in a storage unit in the inhalator, which storage unit is connected to a suitable dosing unit incorporated in the powder inhalator. When the substance is to be released from the hard gelatine capsule or from the dosing unit into the air conduit of the powder inhalator, it is essential that the largest possible quantity of primary particles is obtained in the respirable range, that is, smaller than 5 µm, at flows which can be generated by a patient suffering from disease of the respiratory tract. A sufficient quantity of particles smaller than 5 µm can be obtained to achieve a therapeutic effect by means of a particle disintegrating construction according to US-A-4 524 769, in which a constriction in the nozzle unit increases the flow velocity of the inhalation air and a propeller contributes to an increase in the quantity of particles in the respirable range. This construction implies, however, that movable parts are used in the nozzle unit.

The object of the invention is to accomplish, against this background, a device in powder inhalators of the known kind which is stated in the preamble of claim I, in such way that during inhalation and without the help of movable parts an effective disintegration of powder aggregates into particles within the respirable range is achieved.

This object is attained according to the invention by deflector devices stationarily arranged in the container and/or nozzle unit, which deflector devices are arranged to create a powerful deflecting movement, preferably a rotary movement, for example through the deflector devices comprising one or more helical channel portions.

During the deflection the particles will on the one hand be dashed against the walls of the deflector devices by centrifugal force, whereby large particles or particle aggregates are ground into small particles, and on the other hand collide with each other which results in a mutual grnding action between the particles. The overall result is in that a great quantity of particles can be generated within the respiratory range.

The deflector devices can be arranged in many different ways, in particular in the form of helical channel portions, as will be evident from the claims and the detailed description below.

The invention is described in greater detail below with reference to the accompanying drawings which illustrate some working examples.

Figure I shows an axial cross-section through a first embodiment of a device according to the invention with a helical channel portion in the nozzle unit of the powder inhalator;

Figure 2 shows a corresponding view of a second embodiment with a helical channel portion in the container unit of the powder inhalator;

Figure 3 shows a corresponding view of a third embodiment with a helical channel portion in both the nozzle and the container unit;

Figure 4 shows a corresponding view of a fourth embodiment with double helical channel portions in the container unit, and

Figure 5 shows a corresponding view of a fifth embodiment with double helical channel portions in the container unit and with a helical channel portion in the nozzle unit.

The powder inhalators illustrated in Figures I-5 are all of a known type (see US-A-4524769), named dosage inhalators, and comprise a nozzle unit 2 with a nozzle aperture 2a located at the top and a container unit 3 with a storage chamber 4 for the active compound (which can be refilled through an upper opening sealed by a plug 5 - shown in Figures I, 4 and 5 only) and a dosing unit 6 for delivering a dose of the active compound to an air conduit 7. This air conduit 7 extends from a lower air inlet 8, past the dosing unit 6, where the active compound is emitted to the air flow generated by inhalation, and ends in the lower part of the nozzle unit 2, which consists of a free internal chamber 9 (in the embodiments according to Figures 2 and 4 the chamber 9 occupies the whole space inside the nozzle unit 2).

The likewise known dosing unit 6 comprises essentially a perforated membrane I0 in the form of a plane, rotary membrane whose perforations in connection with the storage chamber 4 are filled with powder substance by means of resilient scrapers II and which in the area of the air conduit 7 emits the powder substance under the action of the air flow generated by inhalation passing through the perforations of the membrane. The dosing unit 6 is operated by an outer, somewhat knurled grip collar I2, which is connected to the rotary membrane I0 so as to transmit the rotary movement. Thus the dosing is achieved by rotating the membrane I0 a fixed distance by means of the grip collar I2.

According to the present invention deflector devices are arranged in the nozzle unit 2 and/or the container unit 3 and are adapted to powerfully deflect the powder-saturated air flow generated by inhalation. In the illustrated embodiments the deflector devices comprise helical channel portions which give the air flow a rotating, helical pattern of motion. The deflector devices are intended to disrupt aggregated particles by means of the centrifugal force generated when the inhalation air flows through the region of the deflector devices. As discussed above, an effective grinding is accomplished, partly by the particles impacting on the deflecting wall surfaces, partly by mutual collisions between the particles. To attain a sufficient rotary motion of the air flow, it is essential that the radial extension of the hollow space in the cross-section area of the nozzle unit 2 is small compared to the radial extension of the deflector devices. Furthermore, the air flow is additionally accelerated by the fact of the nozzle unit 2 being shaped with a constricted cross-section in the region of the deflector devices.

According to Figure I a helical channel portion I3 as described above is arranged at the top of the nozzle unit 2 adjacent the nozzle aperture 2a. The helical channel portion I3, which can be arranged in a detachable liner body in the nozzle unit 2, comprises two interacting helical channel walls I3a and I3b, mutually displaced half a revolution. Furthermore, along the centre line of the helical channel walls there is formed a small, straight hollow space which reduces the flow resistance, at least initially, but which only conducts a small part of the total flow. Consequently air is aspirated into the air intake 8 and the air flow entrains the substance particles in the dosing unit 6, whereupon the particle-saturated air flow enters the chamber 9 of the nozzle unit, where it is mixed with dilution air aspirated through one or more separate air inlets I4 in the side walls of the nozzle unit 2 close to the top end of the container unit 3. Subsequently the composite, particle-saturated air flow is constrained to follow a helical path along the respective helical channel walls I3a, I3b until it leaves the nozzle aperture 2a.

In the embodiment according to Figure 2 the flow proceeds quite freely in the internal chamber 9 of the nozzle unit 2, but the air flow has already been set in helical rotation in the upper part of the air conduit 7 by passing through a similar helical channel portion I5 with helical channel walls I5a, I5b mutually displaced half a revolution. In this case dilution air is aspirated through one or more air inlets I4′ located in the central part of the container unit 3 somewhat above the dosing unit 6, that is, the dilution should take place before the air flow is set in powerful rotation. The rotary movement will continue as a turbulent flow for at least a short distance up the nozzle unit 2 before the air flow leaves the aperture 2a .

The embodiment according to Figure 3 constitutes essentially a combination of Figures I and 2, that is, a helical portion I3 or I5 is arranged both in the upper part of the nozzle unit and in the upper part of the air conduit 7, said dilution air inlets being located either as in Figure I (broken arrow B) or as in Figure 2 (arrow A). The directions of rotation according to Figure 3 are the same in both helical channel portions I3, I5, and consequently they cooperate with each other to achieve a higher rotary speed. In principle it is possible to join the two portions together to form a long continuous helical channel portion. As an alternative, it is possible for the two helical channel portions I3, I5 to have opposite directions of rotation, whereby one deliberately aims to generate a turbulent flow in the chamber 9, with the air flow reversing its direction of rotation. Such turbulent flow can also accomplish effective disintegration of aggregates by frequent mutual collisions.

In the embodiments according to Figure 4 och 5 the dilution air is aspirated from an air inlet I4′ (located somewhat above the dosing unit 6, as in Figure 2) via an envelope surface I6 with helical channel walls surrounding the upper part of the air conduit 7. Consequently the particle-saturated air flow and the dilution air flow enter the chamber 9 separately, although both air streams are set in rotation (in the same or opposite directions). In the embodiment according to Figure 5 an additional rotary motion is achieved in the helical channel portion I3 of the nozzle unit 2. In principle it is conceivable to omit the helical channel portion I5 in the upper part of the air conduit 7 in the embodiments according to Figures 4 and 5, in which case the rotary motion of the dilution air will act on the particle-saturated air flow in the chamber 9. It is also possible to have the helical channel portion in the envelope surface I6 end in the upper part of the air conduit 7.

Besides the above-mentioned effects of the collisions of the particles and aggregates with the channel walls and with other particles and aggregates, the different helical channel portions I3, I5, I6 (in Figures I-5) create a constructing effect which increases the flow velocity and thereby further promotes disintegration. However, the constricting effect, that is, the cross-section area of the helical channel portions, must be adjusted to avoid making the inhalation resistance too great for patients with disease of the respiratory tract, such as asthmatics. In general the total cross-section area can be varied between 5 and 50 mm^2, while the overall length of the helical channel portions can amount to 5-50 mm.

The ratio between the radial extension of the deflector devices and the radial extension of the central hollow space is an essential factor for the efficient disintegration of powder aggregate into particles in the respirable range, that is, the cross-section area of said hollow space must be adjusted to avoid too much of the particle-saturated air flow to pass through the hollow space and couse an inefficient disintegration. Consequently, it is possible to omit the central hollow space to further promote disintegration. The illustrated embodiments show deflector devices in which the radial extension of the hollow space is about I0-20 % of the radial extension of the deflector devices, as appears from Figures I-5. In a cross-section in the region of the deflector devices the ratio of the radial extension of

the central hollow space to that of the deflector devices can be varied essentially between 0-50 % to attain efficient disintegration and also to provide an inhalation resistance which is not too great for patients suffering from disease of the respiratory tract. In the embodiments according to Figures I, 3 and 5 the constricted cross-section in the nozzle unit 2 causes an increased acceleration of the particle-saturated air flow and hence a more efficient disintegration.

The invention is applicable in many ways within the scope of the claims. Thus the deflector devices be placed in different types of powder inhalators (according to the preamble of claim I), and further the deflector devices can be designed in other ways than in the embodiments. In the first place they do not need to generate specifically a rotary or helical flow, but other powerful deflected flow paths are also possible, such, as labyrinthine or meandering flow path. Likewise the channel walls do not have to form continuous guiding surfaces but can consist of a plurality of consecutively arranged, complementary guiding surfaces in the shape of plates or bodies with slightly curved surfaces which together accomplish a powerful deflection of the air flow.

Claims

I. Device in powder inhalators of a kind intended for inhalation of an air flow, which contains pharmacologically active compound in atomized or micronized form and which comprises a nozzle unit (2) with a nozzle aperture (2a) as well as a container unit (3) with a releasing or dosing unit (6) for delivering the active compound, said air flow generated by inhalation being at least partly aspirated through an air conduit (7) in the container unit (3), and said conduit extending from an air inlet (8), communicating with the environment, via said releasing or dosing unit (6) up to said nozzle unit (2), characterized by deflector devices (I3, I5, I6) stationarily arranged in said container (3) and/or nozzle unit (2), said deflector devices, to a substantial extent, extend towards the centre of said devices and being arranged to impart a powerful deflecting movement to the air flow generated by inhaltion.

2. Device according to claim I, characterized in that said deflector devices (I3, I5, I6) are arranged to impart a rotary motion to the air flow generated by inhalation.

3. Device according to claim 2, characterized in that a through hole is arranged along the centre axis of said deflector devices (I3, I5, I6) to lower the flow resistance.

4. Device according to claim 3, characterized in that the ratio of the radial extension of said hole to that of said deflector devices being 0-50 %.

5. Device according to claim I or 2 in which at least one additional air inlet (I4, I4′) is arranged in the container (3) or nozzle unit (2) for aspiration of dilution air into the air flow generated by inhalation between said dosing unit (6) and said nozzle aperture (2a), characterized in that said deflector devices (I5, I6) are arranged to powerfully deflect said dilution air flow and/or the particle-saturated air flow in the region of said air conduit (7).

6. Device according to any of the claims I-5, characterized in that said deflector devices comprise at least one essentially helically formed channel portion (I3, I5, I6).

7. Device according to claim 6, characterized in that at least one helical channel portion (I3), connected to the nozzle aperture (2a), is arranged in said nozzle unit (2).

8. Device according to claim 7, characterized in that the nozzle unit (2) is shaped with a continuously reducing cross-section area towards the nozzle aperture (2a).

9. Device according to claim 6 or 7, characterized in that at least one helical channel portion connected to the nozzle unit (2) is arranged in the region of said air conduit (7).

I0. Device according to claim 7 or 8, characterized in that at least the part of the nozzle unit (2) adjacent the container unit (3) consists of a free, internal chamber (9) through which the air flow generated by inhalation passes.

II. Device according to any of the preceding claims in combination with claim 5, in which said additional air inlet (I4′) is located in the container unit (3) and characterized in that said additional air inlet (I4′) is connected to a separate helical channel portion (I6) which ends in said air conduit (7) or said nozzle unit (2).

I2. Device according to claim I0, characterized in that said separate helical channel portion (I6) is arranged in an envelope surface which surrounds said air conduit (7).

I3. Powder inhalator according to any of claims 6-II characterized in that the cross section area of the respective helical channel portion (I3, I5, I6) is 5-50 mm^2 and that the total length of said helical channel portions is 5-50 mm.

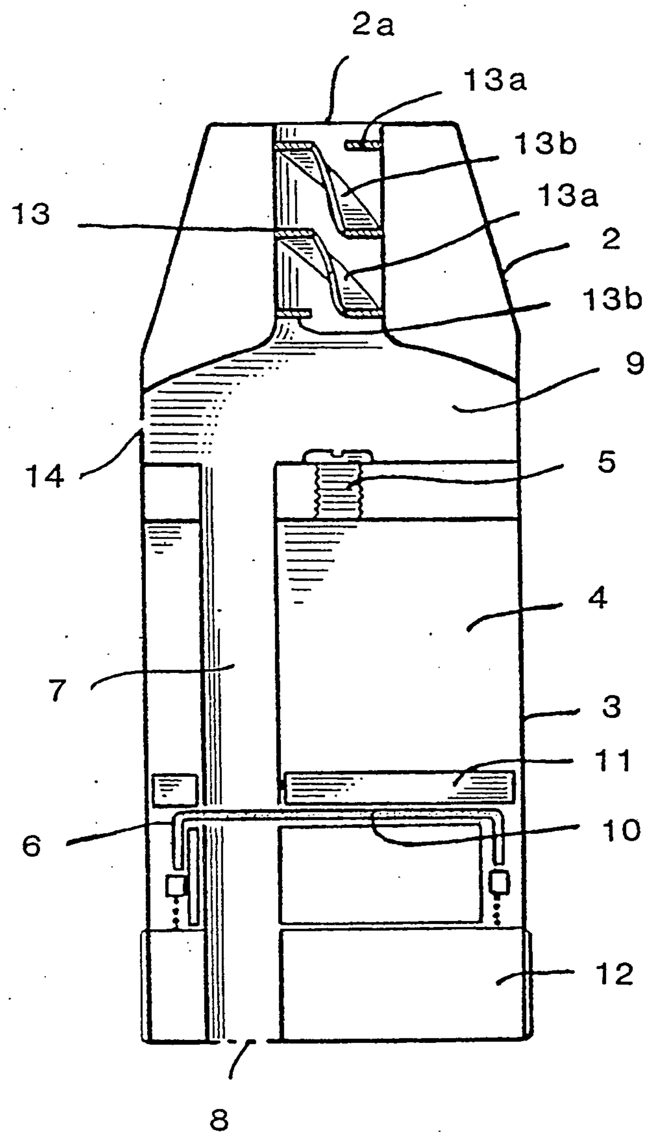

Fig. 1

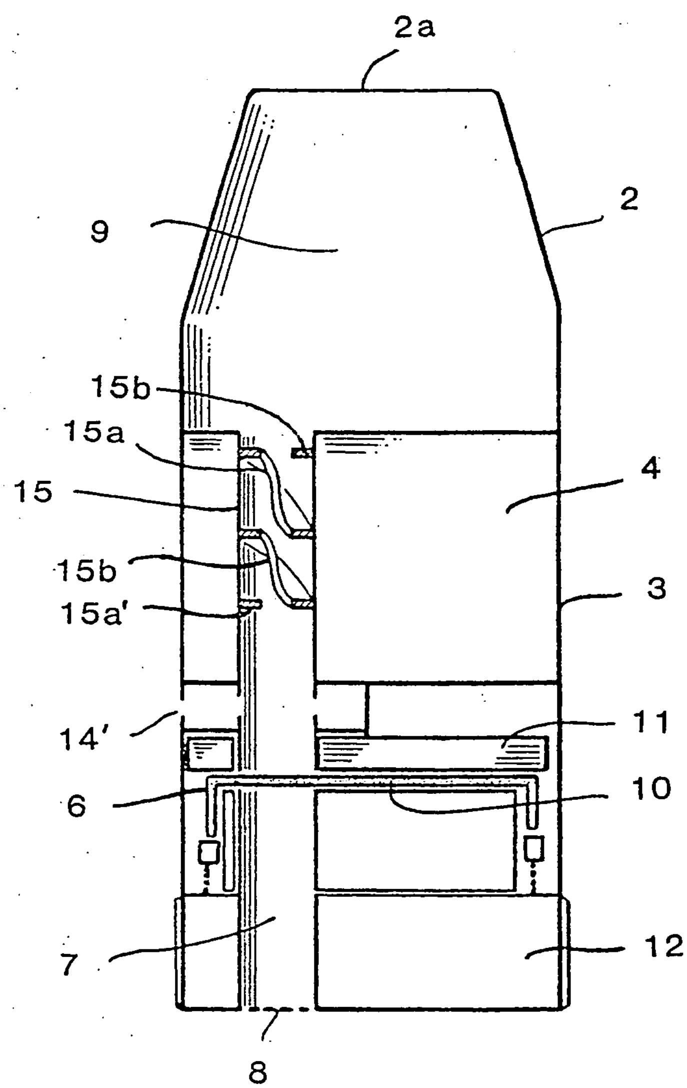

Fig. 2

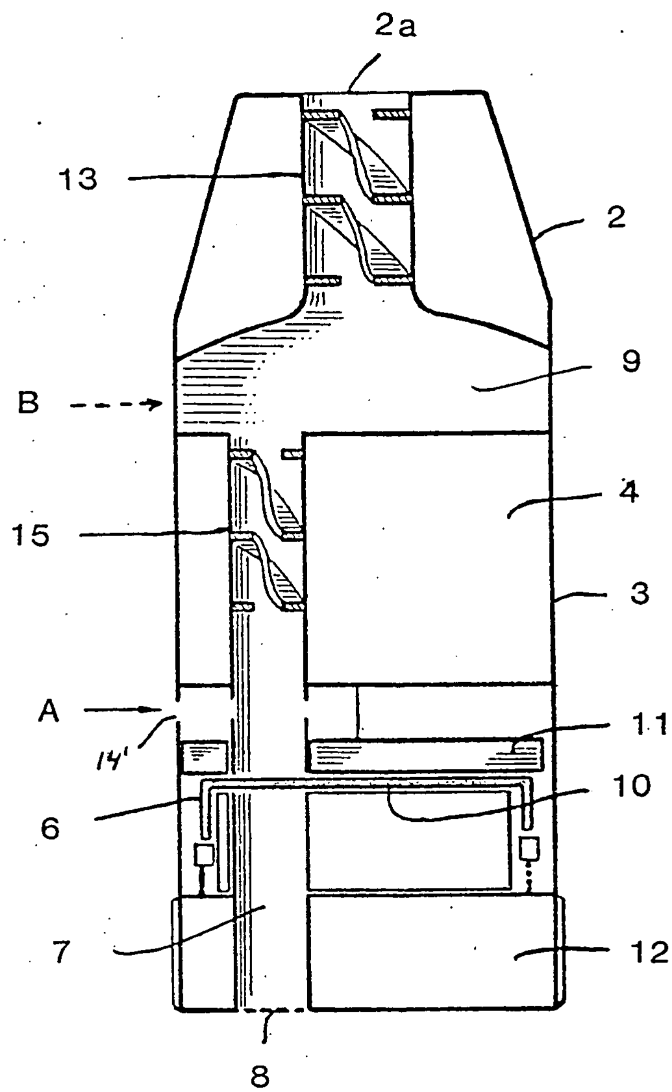

Fig. 3

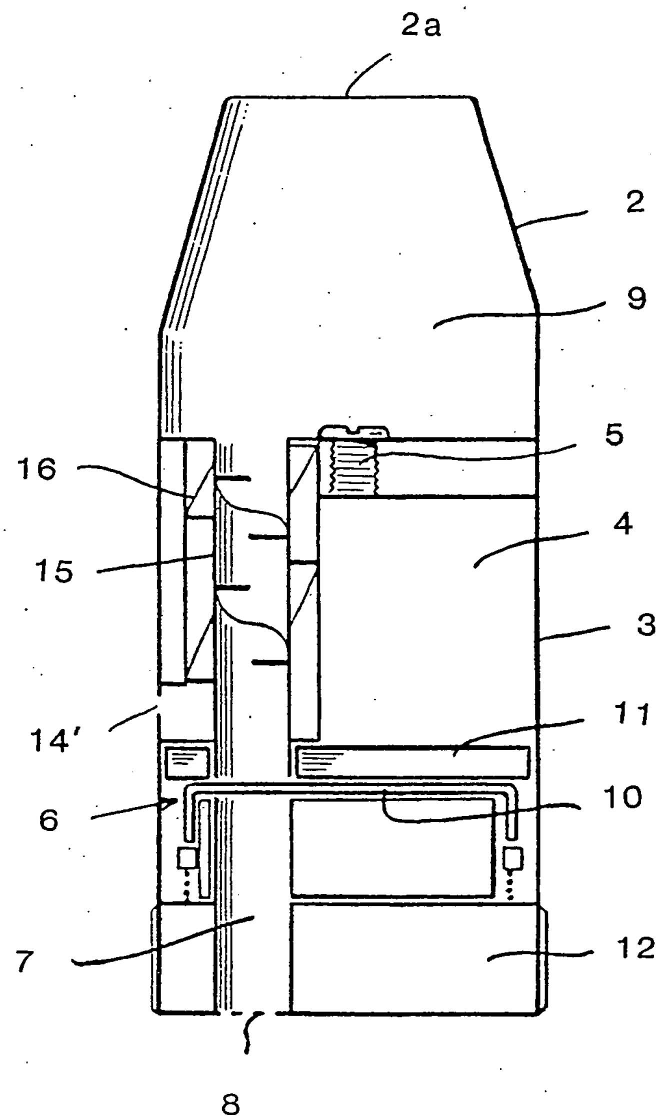

Fig. 4

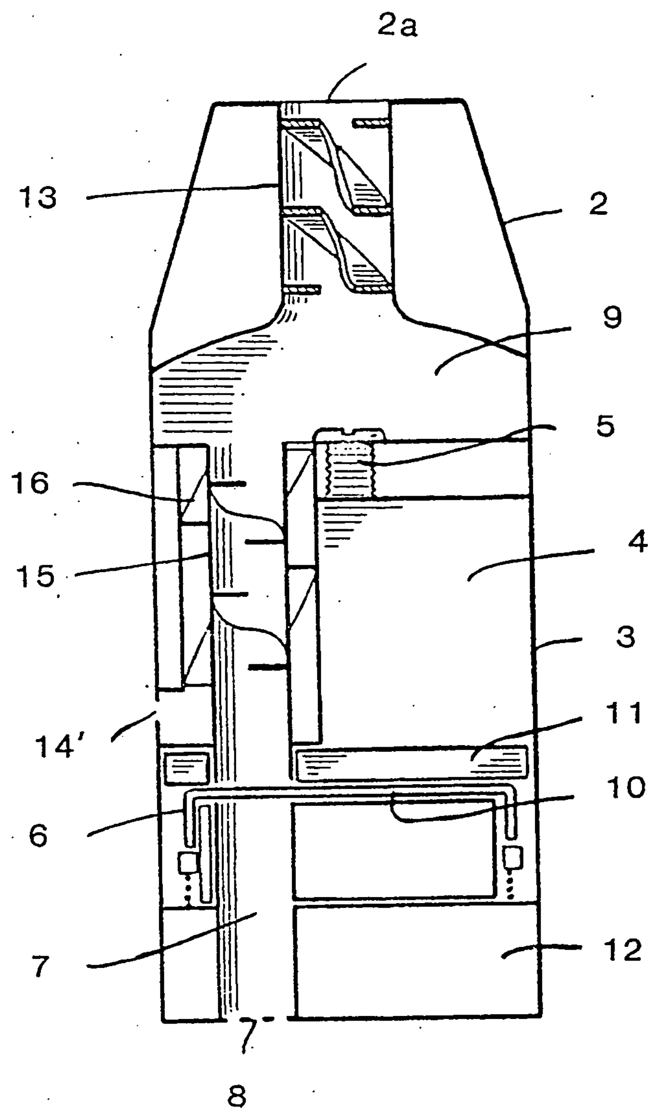

Fig. 5